



Docket No. 24301

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re the patent application of Tomka et al.

Serial No. **09/606,219**

Filing date: June 29, 2000

Title: A method for manufacturing a shape body containing a starch, a homogenized mass containing starch and a device for manufacturing a soft capsule

Group Art Unit **1772** -- Examiner **Nordmeyer**

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Commissioner for Patents

Washington, D.C. 20231

**DECLARATION OF RICO MENARD (37 C.F.R. 1.132)**

I, Rico Ménard, declare that:

1. I am a Physicist ( Eidg. Dipl. Phys. ETH ). I am co-inventor of the Patent Application No. 09/606,219 (the '219 application"). I am the same Rico Ménard who provided a declaration dated September 30, 2002.
2. The '219 application concerns a technical improvement in the production of shaped bodies, in particular soft capsules. The improvement is aimed at substituting the commonly used gelatin as material for forming shaped bodies.
3. The '219-application provides, for the first time, a starch-containing mass which is suitable as a material for forming shaped bodies such as soft capsules. It has surprisingly been found that a homogenized mass containing starch with an amylopectin content of at least 50 % by weight, water and an organic softener and having a limiting viscosity index of at least 40 ml/g, can be formed into

shaped bodies, in particular soft capsules, using a one-step process such as the rotary die process. In the art, the term "homogeneous" is understood as a system comprising only one phase, independent from the number of components.

4. US 5,554,385 (Stroud) has been cited against the '219 application. However, Stroud does not disclose a homogenized mass containing starch with an amylopectin content of at least 50 % by weight, water and an organic softener and having a limiting viscosity index of at least 40 ml/g.
5. Stroud does not provide a composition for the manufacture of shape bodies in which the commonly used gelatin has been completely substituted. To the contrary, Stroud's claims are directed to a soft gelatin capsule. Not more than 85% of the gelatin is replaced by high amylose starch (cf. col. 2, l. 47-49). In contrast hereto, the shape bodies according to the '219 application are made from a gelatin-free mass.
6. Stroud suggests to replace a portion of the gelatin by a high amylose starch, i.e. a starch having an amylose content of at least 50% and those having 90% or more is most preferred (col. 2, l. 26-28). This is also in contrast to the teaching of the '219 application, wherein the use of a starch having an amylopectin content of at least 50% is disclosed. There is only a slight overlap with Stroud insofar as Stroud also suggests the use of a starch having 50% amylose, and thus 50% amylopectin, albeit together with gelatin.
7. The Examiner has stated that it was inherent that the material taught by Stroud has a limiting viscosity index of at least 40 ml/g. This is not correct and would be surprising in view of the above differences. In order to show that the Examiner's assumption is not correct, example 3 of Stroud has been reproduced under my supervision, and the limiting viscosity index of the capsule-forming mass has been measured. In example 3, capsules have been prepared according to example 1 with the exception that a different starch has been used. In example 3, Hylon V starch having an amylose content of 50% was used. Thus, example 3 is the example overlapping with the teaching of the '219 application.

8. In order to reproduce example 3, a mass was prepared from 31,2 wt.-% gelatin, 16,0 wt.-% glycerol and 36 wt.-% water. Thereto, 16,8 wt.-% of Hylon V starch were added at 20°C. The temperature was increased under stirring to 85°C until a homogenous molten mass was obtained. The limiting viscosity index of said mass was measured in accordance with the DIN standard DIN 51562, as also taught in the '219 application (p. 20, 2<sup>nd</sup> para). A limiting viscosity index of 23 ml/g was obtained.
9. Thus, Stroud does not teach a mass according to claim 12 of the '219 application, i.e. Stroud does not teach a mass comprising starch having an amylopectin content of at least 50% by weight and a limiting viscosity index of at least 40 ml/g.
10. Overholt (US-6,258,380) was also cited against the '219 application. However, Overholt does not teach or suggest soft capsules formed from a gelatin-free, starch-containing mass. To the contrary, Overholt suggests a combination of two specific gelatins together with a plasticizer and a moisture retaining agent.
11. Nakajima (US-5,098,606) was also cited against the '219 application. However, Nakajima is not related to shaped bodies such as soft capsules. Nakajima does not disclose homogenized starch-containing masses. Incidentally, it is noted that Nakajima on column 3, l. 27-28, does not refer to glycerine monostearate but to POE glycerine monostearate which is polyoxyethylene glycerine monostearate. This is not the lubricant referred to in claim 13 and 15 of the '219 application.
12. Patel (US-6,248,363) was also cited against the '219 application. Patel teaches a pharmaceutical composition in the form of a solid carrier comprising a substrate and an encapsulation coat on the substrate. Patel does not teach or suggest a mass comprising starch having an amylopectin content of at least 50% by weight and a limiting viscosity index of at least 40 ml/g for forming capsules.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that the making of willful false statements or the like is punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

November 19, 2003

  
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(signature)